



American Academy of Pediatrics  
DEDICATED TO THE HEALTH OF ALL CHILDREN™



**For Immediate Release:** January 17, 2008

The U.S. Food and Drug Administration today issued an advisory strongly *recommending that over-the-counter cough and cold medications not be given to infants and children under two years old because of the risk of life-threatening side effects.* The American Academy of Pediatrics (AAP) supports this recommendation and urges parents to seek safer ways to soothe infants and young children suffering from colds and coughs.

*Studies have shown cough and cold products are ineffective in treating symptoms of children under six years old, and may pose serious risks. A variety of rare, serious health problems have been associated with use of these medications in children, including death, convulsions, rapid heart rates and decreased levels of consciousness. (A review by the U.S. Centers for Disease Control and Prevention of national emergency department visits due to adverse drug events from cough and cold medications will be published in the online version of Pediatrics Jan. 28.)*

*“It is critically important for parents to receive clear information about the risks and lack of benefit from these drugs, and ways to help take care of children suffering from colds and coughs,”* said Renee Jenkins, M.D., FAAP, president of the American Academy of Pediatrics. *“We urge FDA to continue its analysis of the existing data on these medicines intended for children over age 2 and take appropriate action, including initiation of immediate, rigorous scientific studies as needed to determine the drugs’ safety and efficacy.”*

Children metabolize and react to medications differently than adults, often in unanticipated ways. For more than 30 years the AAP has emphasized the importance of studying medicines in pediatric populations. As part of the FDA's ongoing review of over-the-counter cough and cold medications, the AAP in October urged regulators to pursue further studies into whether these drugs have any benefit to children. The AAP also advised labeling that would inform parents that the products have been shown to be ineffective in children under 6 and could lead to serious adverse reactions. Thursday's advisory is an important first step. The FDA expects to announce its recommendation for children ages 2 to 11 in early spring.

While annoying, cough and cold symptoms are usually benign and self-limiting. Over-the-counter cough and cold medications will not cure these illnesses nor shorten their duration. Parents should seek safer ways to nurse their children back to health, Dr. Jenkins said.

“Although these medications have been in use for a long time, now we've learned they have some risks, especially because of the difficulty in determining a safe and accurate dose for small children,” Dr. Jenkins said. “Instead of drugs, there are symptomatic interventions parents can do that are much safer for children.”

*Dr. Jenkins recommended saline nose drops and suctioning bulbs to thin and clear mucus from a baby's nose, and using a cool-mist humidifier. Chest physical therapy can also loosen mucus and may help infants and young children expel mucus. If a child under age 2 develops a fever, consult a pediatrician. For more suggestions on treating children without over-the-counter cough and cold drugs, [www.aap.org/publiced/BR\\_Infections.htm](http://www.aap.org/publiced/BR_Infections.htm).*

[Http://www.aap.org/advocacy/releases/jan08coughandcold.htm](http://www.aap.org/advocacy/releases/jan08coughandcold.htm)



## LA ACADEMIA AMERICANA DE PEDIATRÍA RECOMIENDA ENCARECIDAMENTE PRUDENCIA EN EL USO DE MEDICAMENTOS PARA LA TOS Y CATARRO (OTC). RESUMEN.

**Para hacerlo público inmediatamente. 17 de enero de 2008**

La Food and Drug Administration (FDA) emitió hoy una advertencia recomendando fuertemente que los medicamentos para la tos y el catarro (OTC) no se administren a niños menores de 2 años de edad. Por el riesgo de los efectos secundarios que pueden amenazar la vida.

*Los estudios muestran que los productos para la tos y el catarro son ineficaces en el tratamiento de los síntomas en niños menores de 6 años y pueden provocar serios riesgos. Una variedad de raros, serios problemas de salud se han asociado con el uso de estos medicamentos en niños, incluido muerte, convulsiones, taquicardia y disminución del nivel de conciencia.*

*Es críticamente importante que los padres reciban una información clara acerca de los riesgos y de la falta de beneficio de estos fármacos y la manera de ayudar en el tratamiento del catarro y de la tos a estos niños. El Presidente de la Academia Americana de Pediatría declara: "Nosotros instamos a la FDA a continuar el análisis existente de estos medicamentos **en niños mayores de 2 años** y tomar las acciones apropiadas, incluyendo la iniciación inmediata, de estudios científicos rigurosos necesarios para determinar la seguridad y eficacia de estas drogas".*

Los niños metabolizan y reaccionan a los medicamentos de forma diferente que los adultos. A menudo por vías inesperadas. Durante más de 30 años la Academia Americana de Pediatría ha enfatizado la importancia de los estudios de los medicamentos en la edad pediátrica... *La Academia Americana de Pediatría notifica que los prospectos deberían informar a los padres de la ineficacia en los niños menores de 6 años y de los serios efectos adversos que pueden producir.* El aviso de este jueves (se refiere a la notificación de la FDA del 17 enero de 2008) es un importante primer paso. La FDA espera anunciar las recomendaciones para niños de 2 a 11 años de edad en primavera.

Los síntomas de tos y catarro son generalmente benignos y autolimitados. Los medicamentos para la tos y el catarro (OTC) no curan estas enfermedades ni acortan su duración.....

El Dr. Jenkins (Presidente AAP) recomienda gotas de suero salino y pera de succión para licuar y aspirar el moco nasal y usar humidificadores.....